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Re-evaluation Note REV2018-11

Re-evaluation Project Plan for S-Metolachlor and R-Enantiomer

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
hc.pmra.publications-arla.sc@canada.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
hc.pmra.info-arla.sc@canada.ca

Canada

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Background

In Canada, s-metolachlor and r-enantiomer is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

S-metolachlor and r-enantiomer is a herbicide registered for use on a variety of crops, forests, woodlots and outdoor ornamentals using ground equipment. Products are formulated as emulsifiable concentrates or suspensions. As of 4 April 2018, 19 products containing s-metolachlor and r-enantiomer are registered, including five technical grade active ingredients, two manufacturing concentrates and 12 commercial class end use products.

Under the authority of section 16 of the *Pest Control Products Act*, all registrants of s-metolachlor and r-enantiomer at the time of the initiation of its re-evaluation were notified. Following this, the registrant of s-metolachlor and r-enantiomer technical grade active ingredient in Canada indicated support of most uses included on the labels of end-use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of s-metolachlor and r-enantiomer.

Re-evaluation Project Plan

Anticipated Re-evaluation Timeline

The re-evaluation of s-metolachlor and r-enantiomer is defined as a Category 1 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for s-metolachlor and r-enantiomer is anticipated to be published for consultation by March 2020. The re-evaluation timeline may be updated if, during the risk assessment, the PMRA identifies additional areas of focus that should be considered.

Human Health Risk Assessment

New assessments will be conducted for toxicology, dietary exposure, and residential exposure. Existing assessments with minor updates are considered to be adequate to support the re-evaluation of s-metolachlor and r-enantiomer for the other aspects of human health assessment.

Environmental Risk Assessment

New assessments will be conducted for environmental fate, water modelling and environmental exposure.

Value

The value of s-metolachlor and r-enantiomer will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

Data Requirements

The PMRA has identified the need for the technical registrants to provide data for s-metolachlor and r-enantiomer related to toxicology, dietary exposure and environmental exposure. Relevant data/studies have been requested and received from the technical registrants. Summaries of the data call-ins are found in the PMRA's Public Registry. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested and received from the registrants, to inform the risk assessments.

Additional Information

The PMRA documents can be found in the Pesticides section of Canada.ca. The PMRA documents are also available through the Pest Management Information Service:

Phone:	1-800-267-6315	within Canada, or
	1-613-736-3799	outside Canada (long distance charges apply)
Fax:	1-613-736-3798	
E-mail:	hc.pmra.info-arla.sc@canada.ca	

Appendix I Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of S-Metolachlor and R-Enantiomer

I. Toxicology Data

DACO	Title
4.2.1	Acute Oral
4.2.2	Acute Dermal
4.2.4	Primary Eye Irritation
4.2.5	Primary Dermal Irritation
4.2.6	Dermal Sensitization
4.3.1	Short-term Oral (90-day rodent)
4.3.2	Short-term Oral (90-day and/or 12-month dog)
4.3.3	Short-term Oral (28-day rodent)
4.3.5	Short-term Dermal (21/28-day)
4.3.6	Short-term Inhalation (90-day)
4.4.4	Combined Chronic/Oncogenicity (rodent)
4.5.1	Multigeneration Reproduction (rodent)
4.5.2	Prenatal Developmental Toxicity (rodent)
4.5.4	Genotoxicity: Bacterial Reverse Mutation Assay
4.5.5	Genotoxicity: In vitro Mammalian Cell Assay
4.5.6	Genotoxicity: In vitro Mammalian Clastogenicity
4.5.7	Genotoxicity: In vivo Cytogenetics
4.5.9	Metabolism/Toxicokinetics in Mammals (laboratory animals)

II. Dietary Exposure Data

DACO	Title
6.2	Livestock
7.2	Analytical Methodology (Food Crops & Tobacco)
7.4	Crop Residue Data

III. Environmental Exposure Data

DACO	Title
8.2.3.4	Biotransformation in Soil
8.2.3.5	Biotransformation in Aquatic Systems
8.2.4.2	Laboratory studies of mobility–Aged soil
9.2.4.3	Bee Larvae Toxicity
9.2.4.4	Bee Adult Chronic Toxicity
9.6.2.3	Wild Birds Oral (LD_{50}) Other Species
9.4.8	Bioconcentration/Depuration (Bivalve or Crustacean)
9.8.2	Fresh Water Algae

9.8.4	Terrestrial Vascular Plants
9.8.5	Aquatic Vascular Plants